UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/002,636	10/26/2001	Jose de Jesus de la Fuente	67686/00-602	1974

22206 7590 11/05/2003

FELLERS SNIDER BLANKENSHIP
BAILEY & TIPPENS
THE KENNEDY BUILDING
321 SOUTH BOSTON SUITE 800
TULSA, OK 74103-3318

EXAMINER	
MINNIFIELD, NITA M	
ART UNIT	**PAPER NUMBER**
1645	

DATE MAILED: 11/05/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/002,636	DE LA FUENTE ET AL.	
	Examin r	Art Unit	
	N. M. Minnifield	1645	

-- The MAILING DATE of this communication appears on the cover sh et with th correspondenc address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *14 August 2003* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *9-20* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *9-20* is/are rejected.

7)☒ Claim(s) *14-20* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) *8/14/03* .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

DETAILED ACTION

1. Applicants' amendment filed August 14, 2003 is acknowledged and has been entered. Claims 1-8 have been cancelled. New claims 9-20 have been added. Claims 9-20 are now pending in the present application. All rejections have been withdrawn in view of Applicants' amendment and/or comments with the exception of those discussed below.

2. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

3. Claims 14-20 are objected to because of the following informalities: these claims depend from cancelled claim 1. Appropriate correction is required.

4. Claims 9, 12-15, 19 and 20 are rejected under 35 U.S.C. 102(b) as being anticipated by McGuire et al (5549898) in light of McGarey et al, 1994 (Infection and Immunity; 62/10:4587-4593).

McGuire et al discloses a purified antigenic surface protein of *A. marginale* and that the antigen is useful as a vaccine component for protecting mammals against infection by *A. marginale* (abstract; col. 1; col. 6; col. 17; claims). This protein has a molecular weight of 105 kD (figures; col. 2; col. 4). The protein has been produced by recombinant DNA techniques (cols. 4-8). McGuire et al disclose that the vaccine also contains adjuvants or any other suitable pharmaceutically acceptable carrier or diluent (col. 8). McGuire et al discloses other antigenic (i.e. immunogen from *A. marginale*) and those they are also of use

(col. 4). McGuire et al disclose that in addition to the native proteins isolated and purified from *A. marginale*, the antigens and immunogens according to this invention can comprise active agents formed of one or more such proteins, polypeptide fragments of such proteins, or one or more immunologically similar proteins or polypeptides produced by synthesis or genetic engineering (col. 4). McGuire et al indicate that the purified antigens can be made by recombinant means or artificially synthesized (col. 6). McGuire et al disclose the use of Oklahoma isolates (col. 18).

It is noted that McGarey et al discloses that the MSP1a has a molecular weight of 105 kD (abstract).

The prior art vaccine composition and methods appear to be the same or similar to that claimed by Applicants. Since the Patent Office does not have the facilities for examining and comparing applicants' vaccine composition and methods with the vaccine composition and methods of the prior art reference, the burden is upon applicants to show an unobvious distinction between the material structural and functional characteristics of the claimed vaccine composition and methods of the prior art. See In re Best, 562 F.2d 1252, 195 USPQ 430 (CCPA 1977) and In re Fitzgerald et al., 205 USPQ 594.

Applicant's arguments filed August 14, 2003 have been fully considered but they are not persuasive. Applicants have argued that the new claims are directed to vaccines comprising recombinant MSP1a surface protein antigen in combination with an immunogen derived from *A. marginale* and related methods. However, as set forth above, the prior art does disclose the MSP1a and another protein (i.e. immunogen) from *A. marginale* as well as the related methods.

5. Claims 10, 11 and 16-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over McGuire et al (5549898) in light of McGarey et al, 1994 (Infection and Immunity; 62/10:4587-4593) as applied to claims 9, 12-15, 19 and 20 above, and further in view of Barbet et al 1999.

McGuire et al discloses a purified antigenic surface protein of *A. marginale* and that the antigen is useful as a vaccine component for protecting mammals against infection by *A. marginale* (abstract; col. 1; col. 6; col. 17; claims). This protein has a molecular weight of 105 kD (figures; col. 2; col. 4). The protein has been produced by recombinant DNA techniques (cols. 4-8). McGuire et al disclose that the vaccine also contains adjuvants or any other suitable pharmaceutically acceptable carrier or diluent (col. 8). McGuire et al discloses other antigenic (i.e. immunogen from *A. marginale*) and those they are also of use (col. 4). McGuire et al disclose that in addition to the native proteins isolated and purified from *A. marginale*, the antigens and immunogens according to this invention can comprise active agents formed of one or more such proteins, polypeptide fragments of such proteins, or one or more immunologically similar proteins or polypeptides produced by synthesis or genetic engineering (col. 4). McGuire et al indicate that the purified antigens can be made by recombinant means or artificially synthesized (col. 6). McGuire et al disclose the use of Oklahoma isolates (col. 18). The prior art discloses the claimed invention except for the immunogen being tick cell culture derived *A. marginale.*

However, Barbet et al 1999 teaches a composition comprising MSP1a in PBS (materials and methods), and that the proteins have potential value in diagnostic assays and vaccine value (p. 103; p. 106). Barbet et al teaches that *A. marginale* have been grown in continuous culture in a cell line, IDE8, derived from

embryos of tick *Ixodes scapularis* (p. 102). The art teaches that "[b]ecause the cell culture-derived *A. marginale* organisms were morphologically similar to organisms in naturally infected ticks, it was important to determine which surface antigens, if any, were conserved among the cell culture-, bovine erythrocyte-, and tick salivary-gland-derived *A. marginale* organisms in order to evaluate the potential of using cultured *A. marginale* for future research and for development of improved vaccines and diagnostic tests." (p. 102) Further, Barbet et al teaches that the "[p]resence of these erythrocyte-stage MSPs on cultured, animal-infective rickettsiae suggests that the cell culture-derived *A. marginale* may serve as a source of *A. marginale* of great potential value for basic and applied research. Cultures might be used, for example, to assess antigenic stability and diversity during passage of *A. marginale* through cattle and ticks, to determine whether antigens of biological relevance are expressed selectively on *A. marginale* derived from ticks, to develop transformation systems and gene knockouts to discover rickettsial gene function, for screening of novel therapeutic agents, and for development of improved diagnostic reagents and vaccines. Use of cell culture-derived *A. marginale* may considerably reduce the need to use cattle as a source of rickettsiae." (p. 106). Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to use both the isolated MSP1a antigen and other immunogens even the tick cell culture since the art teaches that the antigenic proteins are on the cell surface. The claimed invention is prima facie obvious in view of the combined teachings of the prior art absent any convincing evidence to the contrary.

6. No claims are allowed.

7. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL.** See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to N. M. Minnifield whose telephone number is 703-305-3394. The examiner can normally be reached on M-F (8:00-5:30) Second Friday Off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Lynette R.F. Smith can be reached on 703-308-3909. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4556 for regular communications and 703-308-4556 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

N. M. Minnifield
Primary Examiner
Art Unit 1645

NMM
October 29, 2003